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DATA EVALUATION RECORD
HONEY BEE - ACUTE CONTACT & ORAL LC_{50} TEST
§141-1

1. **CHEMICAL:** Novaluron PC Code No.: 124002

2. **TEST MATERIAL:** "RIMON" 10 EC Purity: 9.1%

3. **CITATION:**

Author: Gray, A.P.

Title: "RIMON" 10 EC Acute Toxicity to Honey Bees (*Apis mellifera*)

Study Completion Date: January 8, 1998

Laboratory: Huntingdon Life Sciences, Ltd.
P.O. Box 2, Huntingdon
Cambridgeshire, England

Sponsor: Makhteshim Chemical Works Ltd.
P.O.B. 60
Beer-Shave, Israel

Laboratory Report ID: MAK 434/973448

DP Barcode: D285479

MRID No.: 45638408

4. **REVIEWED BY:** Rebecca Bryan, Staff Scientist, Dynamac Corporation

Signature: Rebecca Bryan **Date:** 4/1/03

APPROVED BY: Dana Worcester, Staff Scientist, Dynamac Corporation

Signature: Dana Worcester **Date:** 4/1/03

5. **APPROVED BY:** Bill Evans

Signature: William Evans **Date:** 11/21/03

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6. STUDY PARAMETERS:

Scientific Name of Test Organism: *Apis mellifera*

Age or Size of Test Organism at Test Initiation: Worker honey bees, age not specified

Type of Concentrations: Nominal

Definitive Study Duration: 48 hours

7. CONCLUSIONS:

The honey bee, *Apis mellifera* L., was exposed to "RIMON" 10 EC (a.i. Novaluron) for 48 hours in both oral and contact toxicity tests. In the oral and contact tests, the nominal test concentration was 200 µg/bee. By 48 hours in the oral test, 6.7% mortality was observed in the 200 µg/bee treatment group, compared to 1.7% negative control mortality and 6.7% solvent control mortality. By 48 hours in the contact test, 5.0% mortality was observed in the 200 µg/bee treatment group, compared to 1.7% negative control mortality and 0% solvent control mortality.

The LC_{50} value for the oral test was >200 µg/bee. The LD_{50} value for the contact test was >200 µg/bee. As a result, "RIMON" 10 EC is categorized as practically nontoxic to honeybees on both an acute oral and contact basis.

This acute contact study is classified as Core. This study is scientifically sound and it satisfies the EFED concerning the guideline requirements for a contact toxicity test with honey bees (Subdivision L, §141-1 or 850.3020). **The acute oral study is scientifically sound and is classified as Supplemental.**

Reported Statistical Results - Oral Test:

LD_{50}: >200 µg/bee 95% C.I.: N/A
NOEC: 200 µg/bee Probit Slope: N/A

Reported Statistical Results - Contact Test:

LD_{50}: >200 µg/bee 95% C.I.: N/A
NOEC: 200 µg/bee Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: This acute contact study is classified as Core. This study is scientifically sound and it satisfies the EFED concerning the guideline requirements for a contact toxicity test with honey bees (Subdivision L, §141-1 or 850.3020). The acute oral study is scientifically sound and is classified as Supplemental.

B. Rationale: This acute oral study is scientifically sound but is classified as Supplemental because the study is a non-guideline study and does not fulfill an OPP guideline requirement.

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

1. The age of the worker honey bees were not reported.

10. SUBMISSION PURPOSE: This study was submitted to provide data on the acute oral and contact toxicity of "RIMON" 10 EC (a.i. Novaluron) to honeybees for the purpose of chemical registration.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera, Megachile rotundata,* or *Nomia melanderi*)	*Apis mellifera*
Age at beginning of test:	Worker honey bees, age not specified.
Supplier:	Mr. R. Baker, St Ives, Cambridgeshire, UK
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Stainless steel wire mesh cages (11.5 cm tall x 4.0 cm diameter).
Lighting:	Continuous darkness
Temperature:	24-25°C
Relative humidity:	52-63%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	The definitive limit test was based on results of contact and oral range finding studies. Results not reported.
Reference toxicant test?	Dimethoate
Method of administration:	Oral test: The test solution (200 µg/µL) was prepared in reverse osmosis water. and diluted to 5 mL with a 50% sucrose solution. 200 µL of test solution was provided per cage. Contact test: The test substance was dissolved in 0.5% Tween 80 (prepared with reverse osmosis water), and 1 µL of the test solution was applied to the ventral thorax of each bee using a microapplicator.
Nominal doses:	Oral test: 200 µg/bee Contact test: 200 µg/bee

Guideline Criteria	Reported Information
Controls: Negative control and/or diluent/solvent control	Oral test: negative (untreated) and solvent (50% sucrose solution mixed with water). Contact test: negative (untreated) and solvent (0.5% Tween 80)
Number of colonies per group:	6 replicates; 10 bees/replicate
Solvent: The following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	Acetone, 100 µg/µL
Feeding:	Oral test: After treated solutions were consumed (four and a half hours), bees were supplied with untreated 50% sucrose solution containing water, *ad libitum*. Contact test: A 50% sucrose solution was provided *ad libitum*.
Observations period:	48 hours

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control performance:	Oral test: 1.7% negative control mortality in and 6.7% solvent control mortality by 48 hours. Contact test: 1.7% negative control mortality in and 0% solvent control mortality by 48 hours.

Guideline Criteria	Reported Information
Raw data included:	Data were provided.
Signs of toxicity (if any) were described?	No sublethal effects were observed.

Mortality - Oral Test

Dosage (µg/bee)	No. of bees	Rep.	Cumulative Number of Dead	
			Hour of Study	
			24	48
Test Substance (Novaluron):				
Negative control	10	1	0	0
	10	2	0	0
	10	3	0	1
	10	4	0	0
	10	5	0	0
	10	6	0	0
Solvent control (water/sucrose)	10	1	1	1
	10	2	1	1
	10	3	2	2
	10	4	0	0
	10	5	0	0
	10	6	0	0
200	10	1	1	1
	10	2	2	2
	10	3	0	0
	10	4	0	0
	10	5	0	0
	10	6	1	1

Dosage (µg/bee)	No. of bees	Rep.	Cumulative Number of Dead	
			Hour of Study	
			24	48
Toxic Standard (Dimethoate):				
Negative control	10	1	0	0
	10	2	1	1
	10	3	0	0
Solvent control (Acetone)	10	1	1	1
	10	2	0	0
	10	3	1	1
0.04	10	1	2	2
	10	2	1	1
	10	3	1	2
0.16	10	1	6	6
	10	2	5	5
	10	3	6	6
0.64	10	1	10	10
	10	2	10	10
	10	3	8	9

Observations: By 48 hours, 6.7% mortality was observed in the 200 µg/bee treatment group, compared to 1.7% negative control mortality and 6.7% solvent control mortality.

Mortality - Contact Test

Dosage (µg/bee)	No. of bees	Rep.	Cumulative Number of Dead	
			Hour of Study	
			24	48
Test Substance (Novaluron):				

Dosage (ug/bee)	No. of bees	Rep.	Cumulative Number of Dead	
			Hour of Study	
			24	48
Negative control	10	1	0	0
	10	2	0	0
	10	3	0	1
	10	4	0	0
	10	5	0	0
	10	6	0	0
Solvent control (Tween 80)	10	1	0	0
	10	2	0	0
	10	3	0	0
	10	4	0	0
	10	5	0	0
	10	6	0	0
200	10	1	0	0
	10	2	0	0
	10	3	0	0
	10	4	0	0
	10	5	1	1
	10	6	1	2
Toxic Standard (Dimethoate):				
Negative control	10	1	0	0
	10	2	1	1
	10	3	0	0
Solvent control (Acetone)	10	1	1	1
	10	2	1	1
	10	3	0	0
0.04	10	1	5	5
	10	2	0	0
	10	3	0	0
0.16	10	1	4	4
	10	2	5	5
	10	3	6	7

Dosage (µg/bee)	No. of bees	Rep.	Cumulative Number of Dead	
			Hour of Study	
			24	48
0.64	10	1	10	10
	10	2	9	10
	10	3	10	10

Observations: By 48 hours, 5.0% mortality was observed in the 200 µg/bee treatment group, compared to 1.7% negative control mortality and 0% solvent control mortality.

Statistical method: The LD_{50} values were estimated based on mortality and sublethal effects data in the oral and contact toxicity tests.

Reported Statistical Results - Oral Test:

LD_{50}: >200 µg/bee 95% C.I.: N/A
NOEC: 200 µg/bee Probit Slope: N/A

Reported Statistical Results - Contact Test:

LD_{50}: >200 µg/bee 95% C.I.: N/A
NOEC: 200 µg/bee Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical method: Statistical analyses were not required, as it could be visually determined that there were no effects of treatment on mortality in both the acute oral and contact tests.

Results - Oral Test:

LC_{50}: >200 µg/bee 95% C.I.: N/A
NOEC: 200 µg/bee Probit Slope: N/A

Results - Contact Test:

LD_{50}: >200 µg/bee 95% C.I.: N/A
NOEC: 200 µg/bee Probit Slope: N/A

14. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to the study authors. **The LC_{50} value for the oral test was >200 µg/bee. The LD_{50} value for the contact test was >200 µg/bee. As a result, "RIMON" 10 EC is categorized as practically nontoxic to honeybees on both an acute oral and contact basis.**

For the oral toxicity test, the 48-hour LD_{50} of the toxic standard, dimethoate, was 0.14 µg/bee. For the contact toxicity test, the 48-hour LD_{50} of the toxic standard, dimethoate, was 0.15 µg/bee.

15. REFERENCES:

Gough, H.J., McIndoe, E.C. & Lewis, G.B. (1994) The use of dimethoate as a reference compound in laboratory acute toxicity tests on honey bees (*Apis mellifera* L.) 1981-1992. *Journal of Apricultural Research*, 33(2): 119-125.

Thompson, W.R. & Weil, C.S., (1952) On the construction of tables for moving average interpolation *Biometrics*, 8: 51-54.